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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/742,690	12/20/2000	Paul James Davis	C7535(V)	5544

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UNILEVER
PATENT DEPARTMENT
45 RIVER ROAD
EDGEWATER, NJ 07020

EXAMINER	
RAO, MANJUNATH N	

ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 03/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/742,690	DAVIS ET AL.	
	Examiner	Art Unit	
	Manjunath N. Rao, Ph.D.	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 December 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,5,8,12 and 14-17* is/are pending in the application.

4a) Of the above claim(s) *15 and 16* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,5,8,12,14 and 17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-3, 5, 8, 12, 14-17 are currently pending and are present for examination.

Claims 1-3, 5, 8, 12, 14, 17 are now under consideration. Claims 15-16 remain withdrawn from consideration as being drawn to non-elected group.

Applicants' amendments and arguments filed on 12-10-03, have been fully considered and are deemed to be persuasive to overcome the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 2, 8, 12, 14, 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shoseyov et al. (US 5,719,044, 2-17-1998), and Bettiol et al. (WO 99/57155, Nov. 1999).

Claims 1, 2, 8, 12, 14, 17 are drawn to a fusion protein comprising CBD obtained from a source such as *Clostridium* and a domain having a high binding domain for another ligand with a binding equilibrium constant of less than 10^{-4} M, and wherein the high binding domain is an antibody or a fragment of an antibody directed to micro-particles loaded with a benefit agent, wherein the two domains are linked through a linker comprising 2-5 or 2-15 amino acids.

Shoseyov et al. teach a similar fusion protein comprising a CBD obtained from *Clostridium* and a high affinity binding domain, wherein the high binding domain is a multispecific antibody of heavy chain type directed to any desired protein or enzymes such esterases, proteases, lipases etc. or hormones (see column 4, lines 45-58 or claims 4-5 and figure 12), and wherein the CBD and the high affinity binding domain are linked by means of (cleavage site) linker comprising 2-5 or 2-15 amino acids (see column 5 lines 24-33). However, the reference does not teach that fusion proteins comprising the CBD and an antibody specifically directed to benefit agents used in detergents.

Bettiol et al. reference clearly teaches fusion proteins comprising a CBD and a peptide linked through an amino acid linker and method of making such fusion proteins and their use in detergent compositions. The reference teaches that the peptide portion of the fusion protein can be an anti-microbial peptide or a catalytically active anti-microbial enzyme which when mixed with detergent composition can sanitize the surface of the fabric. The reference of does not teach the use of antibodies in the fusion protein.

Combining the teachings of both above references it would have been obvious to one of ordinary skill in the art to make fusion proteins comprising a CBD and antibodies that specifically bind to micro-particles loaded with benefit agents using the procedures taught by above references such that a variety of benefit agents enclosed in a common μ-particle can be delivered directly to the surface of the fabric that is being washed using the detergent comprising said fusion proteins as demonstrated by Bettiol et al. to deliver the benefit of sanitization on to the surface of the fabric. One of ordinary skill in the art would have been motivated to do so as CBD can bind to the target region on the fabrics (cellulose fibers) and direct the action of either

the peptide or the micro-particles loaded with benefit agents, on the mark where it is needed, on the actual surface of the fabric. One of ordinary skill in the art would have had a reasonable expectation of success as the references teach the methods of making and the method of use of fusion proteins comprising a CBD and a peptide or antibody and the benefits of such fusion proteins.

Therefore, the above invention would have been *prima facie* obvious to one of ordinary skill in the art.

Applicants may argue that the reference of Shoseyov et al. does not teach every limitation of the claimed invention. Applicants may argue that the reference does not disclose that binding equilibrium constant for the high affinity binding domain with its ligand is lower than 10^{-4} M. However, such an argument would not be persuasive to overcome the rejection because as the inventions are so closely related i.e., a fusion protein comprising a CBD fused to an antibody, Examiner takes the position that the fusion protein in the reference inherently has the same bio-physical characteristic (binding affinity being lower than 10^{-4} M) as that of the fusion protein claimed in the instant invention even though such limitation are not clearly mentioned in the reference. Since the Office does not have the facilities for examining and comparing applicants' protein with the protein of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the protein of the prior art does not possess the same material structural and functional characteristics of the claimed protein). See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *In re Fitzgerald* et al., 205 USPQ 594.

In response to the previous rejection of claims 1-3, 5, 8, 12, 14-17 under 35 U.S.C. 102(b), applicant continues to argue that the reference of Shoseyov et al. does not disclose each and every element of claim 1 and therefore cannot anticipate claim 1. Without acquiescing to such argument, Examiner has now rejected the claims as obvious over the same reference.

Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Shoseyov et al. and Bettiol et al. as applied to claims 1, 2, 8, 12, 14, 17 above, and further in view of Linder et al. (PNAS, 1996, Vol. 93:12251-55). Claim 3 of this application is drawn to a fusion protein comprising CBD and a domain having high binding affinity for another ligand (claim 1), wherein the CBD is obtained from *T.reesei*, wherein the domain having a high binding affinity is directed to a "benefit agent" selected from a group as in claim 8, or at the fabric or at polyester etc. or at a specific part of a fabric or at micro-particles loaded with a benefit agent wherein the CBD is connected to the domain by an amino acid linker of 2-15 or 2-5 amino acids.

The reference of Shoseyov et al. and Bettiol et al. as it applies to claims 1, 2, 8, 12, 14, 17 has already been discussed above. However, the reference does not teach such fusion proteins comprising the CBD isolated from *T.reesei*.

Linder et al. teach CBD of *T.reesei*. The reference teaches that the *T.reesei* CBD exhibits reversible binding to crystalline cellulose, can be eluted from cellulose by simple dilution and that the binding is temperature sensitive with an increased affinity at lower temperatures.

With the teachings of the above references in hand it would have been obvious to one of ordinary skill in the art to use the CBD taught by Linder et al. in place of the CBD taught by

Shoseyov et al. to make a fusion protein comprising *T.reesei* CBD linked to an antibody of interest. With a fusion protein comprising a CBD ---which is capable of binding to a cellulose matrix and whose binding can be easily manipulated by just change of temperature—linked to an antibody through an amino acid linker, as taught by Shoseyov et al. it would have been obvious to one of ordinary skill in the art to make a similar fusion protein for affinity purification of a benefit agent such as protein or a peptide wherein the antibody is directed to said protein or peptide. One of ordinary skill in the art would have been motivated to do so as Linder et al. teach that the binding reaction of *T.reesei* CBD to crystalline cellulose is reversible which property can be made use of in elution of fusion proteins bound to cellulose matrix during affinity purification procedure. One of ordinary skill in the art would have been further motivated to use the *T.reesei* CBD as the above reference further teaches that the binding is reversible and temperature sensitive which makes it easier to set the conditions for binding and elution. One of ordinary skill in the art would have a reasonable expectation of success since Shoseyov et al. teach a method of making fusion protein comprising a CBD and Linder et al. teach the CBD from *T.reesei.*

Therefore, the above invention would have been *prima facie* obvious to one of ordinary skill in the art.

Applicant has made no remark on the above rejection.

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Shoseyov et al. and Bettiol et al. as applied to claims 1, 2, 8, 12, 14, 17 above, above and further in view of Frenken et al. (WO 94/25591, 10-11-1994) and the common knowledge in the art of laundry

detergents. Claim 5 of this application are drawn to a fusion protein comprising CBD and a domain having a high binding affinity for another ligand, wherein the CBD is connected to the other domain by an amino acid linker of 2-15 or 2-5 amino acids, wherein the CBD is obtained from *Clostridium*, and wherein the high binding domain is an antibody or a antibody fragment such as a Heavy Chain antibody as found in Camelidae.

On the whole it appears that fusion proteins comprising CBDs were well known in the art of detergent compositions. Similarly, the technique of using enzymes, antibodies or antibody fragments as part of detergent compositions also appears to be well known in the art of detergent composition, even though the use of them as fusion proteins with a CBD was less known.

The references of Shoseyov et al. and Bettiol et al. as it applies to claims 1, 2, 12, 14, 17 has already been discussed above.

Frenken et al. teach in general, production of antibodies or functionalized fragments derived from heavy chains of Camelidae antibodies.

With all the above references in hand it would have been simply obvious to one of ordinary skill in the art to combine the teachings of the above references and arrive at the invention claimed in claim 5. As stated earlier, Shoseyov et al. teach a fusion protein comprising a CBD and an antibody. Using the reference of Frenken et al. which teaches the advantages of Camelidae antibodies and its large scale production, it would have been obvious to one of skill in the art to use the method taught by the reference and make any antibody of interest to use it in the fusion protein. Combining the teachings of all the three references it would have been obvious to one of ordinary skill in the art to make fusion proteins comprising a CBD and Heavy

Chain antibodies obtained by Camelization process as taught by Franzen et al. that specifically bind to micro-particles loaded with benefit agents, such that said benefit agents can be delivered directly on the surface of the fabric as demonstrated by Bettiol et al. to the deliver the benefit of sanitization on to the surface of the fabric. One of ordinary skill in the art would have been motivated to do so as Franzen et al. teach the advantages of "camelization" procedure. One of ordinary skill in the art would have had a reasonable expectation of success as all the references teach the methods of making and the method of use of fusion proteins comprising a CBD and a peptide or antibody and the benefits of such fusion proteins.

Therefore, the above invention would have been *prima facie* obvious to one of ordinary skill in the art.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the Examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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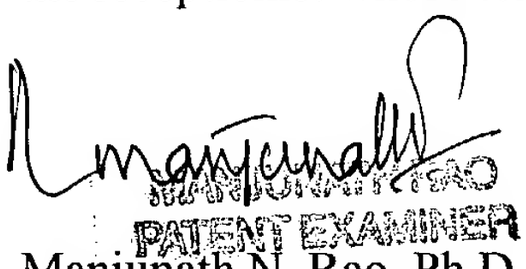
Conclusion

None of the claims are in condition for allowance. In the amendment filed on 12-10-03, applicants have provided arguments that were persuasive to overcome the rejection under 35 U.S.C. 102(b) and therefore Examiner has withdrawn said rejection. However, he has reinstated previous rejection under 35 U.S.C. 103(a) as obvious.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Manjunath N. Rao, Ph.D. whose telephone number is 571-272-0939. The examiner can normally be reached on 6.30 a.m. to 3.00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy can be reached on 571-272-0939. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.



Manjunath N. Rao, Ph.D.
March 2, 2004